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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,074	09/05/2000	Michio Naka	10873.164 USC2	8424

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MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER
ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
1743	15

DATE MAILED: 03/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/655,074	Applicant(s) NAKA ET AL.	
	Examiner Lyle A Alexander	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9-18,28-33,38-44 and 46-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,12-17,28-31,38-44,46-53,64,66-71 and 565* is/are rejected.

7)☒ Claim(s) *7,10,11,18,32,33,54,55,65 and 72* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

In response to the 3/4/03 remarks and amendments, the search was up dated and the following new references were found and are applied in the new rejection below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7,9-18,28-33,38-44 and 46-72 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,180,062. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a test device having a suction pressure generator comprising a flexible cover, an analytical region and a fluid passage. Also, both devices also have the same claimed dimensions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50,69-71 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Davis or Ebersole.

Davis teaches a device(10) comprising a half tubular cavity(13) terminating in a half-bulb cavity(14). Indicators(16) are applied within the cavity(13). Sample is drawn into the cavity by depression of bulb cavity(14) and the sample reacts with indicator(16).

Ebersole teaches a device that has a tapered tip(42) that contacts the sample, an extended tubular portion(40) and a compressible upper chamber(38) respectively. Column 9 teaches the chamber(38) is compressed to draw fluid into the tubular portion(40) that contains analytes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 51-53,60-64,66-68 and 71 rejected under 35 U.S.C. 103(a) as being unpatentable over Davis or Ebersole.

See Davis and Ebersole supra.

The art is silent to the relative flow rates within each portion of the device and multiple channels.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable has predictable and well known results. The selection of a flow rate has the predictable results of varying the reaction/incubation/reagent interaction time. The selection of a flow rate is a result effective variable.

It would have been within the skill of the art to modify Davis or Ebersole and select the relative flow rates of each portion of the device as optimization of result effective variable to gain the advantages of varying the reaction/incubation/reagent interaction.

Claims 9,12-17,28-31,38-44, 46-49 and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis or Ebersole in view of Apicella.

Davis and Ebersole supra.

The art is silent to the dimensions of the devices, the relative flow rates within each portion of the device and multiple channels.

The court decided In re Yount (80 USPQ 141) "...that mere size is not matter of invention...". Additionally, Apicella teach an analytical device having flexible compartments that are depressed to mix the sample and reagent. Apicella teaches in the last paragraph of column 2 suitable shapes and sizes for such devices are rectangular in the range of 2 to 6 inches or 50.8-152.4 mm.

It would have been within the skill of the art to modify Davis or Ebersole in view of Apicella and make the devices have lengths or widths in the range of 50mm as selection of a suitable dimension in light of the size in not a matter of invention.

Additionally, it is advantageous to make device as small as possible to gain the advantages of greater portability and lower shipping cost. It would have been within the skill of the art to further modify Davis or Ebersole and select a thickness of between 1 to 5 mm and width between 5 to 20 mm as engineering design choice since the size is not a matter of invention and to gain the above advantages.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable has predictable and well known results. The selection of a flow rate has the predictable results of varying the reaction/incubation/reagent interaction time. The selection of a flow rate is a result effective variable.

It would have been within the skill of the art to modify Davis or Ebersole and select the relative flow rates of each portion of the device as optimization of result effective variable to gain the advantages of varying the reaction/incubation/reagent interaction.

Allowable Subject Matter

Claims 7,10-11,18,32-33,54-55,72 and 65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Anderson teach a device comprising a fluid inlet, a pump and a reagent region. This reference is not applicable because it fails to teach the claimed sequence of a fluid inlet, an analytical region and a pump.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9319 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.

Lyle A Alexander
Primary Examiner
Art Unit 1743

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March 15, 2003